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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,880	07/29/2003	Harry Leneau	29792-73218	5579

22446 7590 05/04/2006

ICE MILLER LLP
ONE AMERICAN SQUARE, SUITE 3100
INDIANAPOLIS, IN 46282-0200

EXAMINER	
HAWES, PILI ASABI	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,880	LENEAU, HARRY	
	Examiner	Art Unit	
	Pili A. Hawes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-13 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-13 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7-21-03, 7-16-04, 12-20-04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of the Information Disclosure Statement(s) filed 07-29-2003, 07-16-2004, 12-20-2004 is acknowledged. Claims 1-13 are pending in this action. Claims 1-13 are rejected.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6607745. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are directed toward a method for relieving joint pain or other discomforts associated with arthritis or fibromyalgia by administering an oral

composition of hyaluronic acid. The hyaluronic acid is administered with a food acceptable carrier. The only difference between the patented claims and the instant claims is directed to treating joint pain or discomfort associated with joint disorders, while the patented claims recite the specific joint disorder such as arthritis and fibromyalgia. However the scope of the instant claims are overlapping with the patented claims as is evident by claims 5-6 which recite the arthritic conditions as the joint disorder.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for joint disorders such as arthritis, osteoarthritis, rheumatoid arthritis, and fibromyalgia, does not reasonably provide enablement for all joint disorders. Joint disorders include carpal tunnel syndrome, canine hip dysplasia, systemic lupus erythematosus, tendonitis, and bursitis among others. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The specification has not shown that the composition is effective in carrying out the method of treating joint discomfort and joint pain associated with all joint disorders.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 9 recites the effective amount of hyaluronic acid in the composition is 1-6 mg. However this limitation is not disclosed in the specification. The specification discloses that the concentrate can contain 1-10 mg of hyaluronic acid (page 4, line 20). The specification further discloses that each patient in the example received 1-4 mg of hyaluronic acid (page 4, line 30). However there is nowhere in the specification that discloses the 1-6 mg claimed in claim 9.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Pierce US 6924273.

Pierce teaches a method of treating or preventing osteoarthritis, joint inflammation and pain by administering to a mammal hyaluronic acid (col. 4, lines 46-55 and col. 5, lines 30-35). The reference teaches using 0.1-.5 mg of hyaluronic acid per kg of body weight in the composition (col. 9, lines 34-39). The reference teaches the

effective amount for canines range from 2-8 mg. The compositions can be in the form of a paste, gel, tablets, and capsules (col. 11, lines 59-60). Example discloses a hyaluronic composition that comprises water as the food acceptable carrier (col. 17, lines 1-15).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

P. A. Hawes
Examiner-1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

7-29-2003

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 29792-73218	SERIAL NO. Unknown
	APPLICANT Harry Leneau.	
	FILING DATE July 29, 2003	GROUP Unknown

U.S. PATENT DOCUMENTS

*Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if
	AA	4,808,576	Feb. 28, 1989	Schultz et al.			
	AB	5,470,576	Nov. 28, 1995	Aoki et al.			
	AC	5,633,003	May 27, 1997	Cantor			
	AD	6,159,955	Dec. 12, 2000	Ascular et al.			
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation Yes No
	AL						
	AM						
	AN						
	AO						
	AP						

OTHER REFERENCES *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	AR	"Hyaluronan (Hyaluronic acid, Synvise, Hyalgan)" from website *www.midwestarthritis.com/html/hyaluronic_acid.htm*
	AS	Wen, Dennis Y., "Intra-articular Hyaluronic Acid Injections for Knee Osteoarthritis", *American Family Physician*, 60, 565-70, 572, (2000)
	AT	Marte, Jim, "Green Plaster, A Webpage Resource For Orthopaedic Technologists. Intra-Articular Hyaluronic Acid Injections for Knee Osteoarthritis", from website *home.earthlink.net/~jim56/otchyal.htm*
	AU	"Arthritic Disorders", *www.advanhealth.com/arthritis.htm*
	AV	"Arthritic Disorders and Treatments", from website *www.s.org/brarthdis.html*
	AW	"Hillbrook Wellness Institute", from website *www.hillbrook.com*
	AX	"Glucosamine and Chondroitin", from website *chemistry.about.com/science/chemistry/library/weekly/aa120400a.htmi, (12/00)*
	AY	"Fibromyalgia Basics - Symptoms, Treatments and Research", from website *www.fmnetnews.com/pages/basics.html*
	AZ	"Hyaluronic Acid (Hyaluronan)", from webiste *www.apharma.it/site/html/hyaluronic.htm*

Examiner	Date Considered
	4-27-2006

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

BASED ON FORM PTO 1449

4-24-2005

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.	SERIAL NO.
29792-73218	Unknown
APPLICANT: Harry Leneau.	
FILING DATE: July 29, 2003	GROUP: Unknown

U.S. PATENT DOCUMENTS

*Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	BA						
	BB						
	BC						
	BD						
	BE						
	BF						
	BG						
	BH						
	BI						
	BJ						
	BK						

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation Yes No
	BL						
	BM						
	BN						
	BO						
	BP						

OTHER REFERENCES *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	BR	"Hyaluronic Acid", from website *www.bioiberica.com/eng/mp/hyaluronic.htm*
	BS	"Hyaluronic acid", from website *www.medmedia.com/02/68.htm*
	BT	"Hyaluronic Acid" from website *uconnsportsmed.uchc.edu/hyaluronic_acid.htm*
	BU	
	BV	
	BW	
	BX	
	BY	
	BZ	

Examiner: [signature] Date Considered: 4-27-2005

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

BASED ON FORM PTO 1449

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	10/629,880
Filing Date	July 29, 2003
First Named Inventor	LENEAU, Harry
Art Unit	1615
Examiner Name	PAGE, T.
Attorney Docket Number	p00903-us-01

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-			
		US-			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3] Number[4] Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
TP		WO 00/44367	08/03/2000	Brown, et al.		

Examiner Signature		Date Considered	4-27-2005

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (09-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	10/629,880
Filing Date	July 29, 2003
First Named Inventor	LENEAU, H.
Art Unit	1615
Examiner Name	Page, T.
Attorney Docket Number	P00903US01

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
pA	DA	US- 4,303,676	12-02-1981	Balazs	
		US-			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
pA	DB	WO 97/25051	07-17-1997	Turley		
pA	DC	WO 92/22585	12-23-1992	Gallina		
pA	DD	JP9262057 (abstract)	10-07-1997	Jennal		

Examiner Signature		Date Considered	4-29-2005

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

Notice of References Cited	Application/Control No. 10/629,880	Applicant(s)/Patent Under Reexamination LENEAU, HARRY	
	Examiner Pili A. Hawes	Art Unit 1615	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,924,273	08-2005	Pierce, Scott W.	514/54
*	B	US-6,607,745	08-2003	Leneau, Harry	424/439
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

PTO/SB/21 (09-06)
Approved for use through 03/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission: 15

Application Number	10/629,880
Filing Date	July 29, 2003
First Named Inventor	LENEAU, Harry
Art Unit	1615
Examiner Name	HAWES, Pili Asabi
Attorney Docket Number	P00903-US-01 (21934.0001)

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☑ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☑ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☑ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please Identify below):

Return postcard; Check No. 323455 in the amount of $640.00 for terminal disclaimer fee and extension of time fee

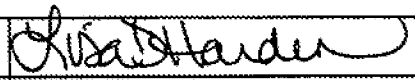
Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	ICE MILLER LLP		
Signature			
Printed name	Mark C. Reichel		
Date	November 3, 2006	Reg. No.	53,509

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name	Lisa D. Harden	Date	November 3, 2006

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

ICEMILLER LLP
LEGAL COUNSEL

November 3, 2006

WRITER'S DIRECT NUMBER: (317) 236-5882
DIRECT FAX: (317) 592-4606
INTERNET: MARK.REICHEL@ICEMILLER.COM

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

I hereby certify that this correspondence is being deposited with the United States Postal Services as first class mail in an envelope addressed to: Mail Stop: Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 3, 2006.

Lisa D. Harden
Printed or typed Name of person signing certificate

(Signature)

November 3, 2006
Date of Signature

MAIL STOP: AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

1/08/2006 CNGUYEN2 00000031 10629880
1 FC:2253 510.00 OP

Refund Ref:
11/08/2006 CNGUYEN2 0000154701

CHECK Refund Total: $65.00

Re:

Invention:	INGESTION OF HYALURONIC ACID FOR IMPROVED JOINT HEALTH
Inventors:	LENEAU, Harry
Serial No.:	10/629,880
Filed:	July 29, 2003
Art Unit:	1615
Examiner:	HAWES, Pili Asabi
Confirmation No:	5579
Our Docket No.:	P00903-US-01 (21934.0001)

RESPONSE TO OFFICE ACTION

In response to the Office Action mailed May 4, 2006 (the "Office Action"), Applicant files a terminal disclaimer, petitions for an extension of time of three (3) months. Applicant encloses a check in the amount of $640.00 for the terminal disclaimer fee ($130.00) and extension of time fee ($510.00). The listing of claims starting on page 2 will replace all prior versions and listings of the claims in the above-referenced patent application (the "Application"). The Remarks begin on page 4 of this paper.

CLAIMS

I claim:

1. (Original) A method for relieving joint pain or other discomforts associated with joint disorders in a warm-blooded vertebrate comprising the step of delivering to said vertebrate by oral ingestion a nutritional supplement consisting essentially of an effective amount of hyaluronic acid, or a salt or digest thereof, and a food acceptable carrier, wherein the effective amount of hyaluronic acid, or a salt or digest thereof, is from about 0.1 μg to about 400 μg/kg of body weight.

2. (Original) The method of claim 1 further comprising the step of adding the hyaluronic acid, or a salt or digest thereof, to the carrier, and wherein the carrier comprises food or water.

3. (Original) The method of claim 1 wherein the nutritional supplement is provided in capsule form.

4. (Original) The method of claim 1 wherein the warm-blooded vertebrate is a human, or an equine, canine, or feline species.

5. (Original) The method of claim 1 wherein the joint pain is the result of an arthritic condition.

6. (Original) The method of claim 5 wherein the arthritic condition is selected from the group consisting of osteoarthritis and rheumatoid arthritis.

7. (Original) The method of claim 1 wherein the joint pain is the result of an inflammatory condition involving skeletal or musculoskeletal structures.

8. (Original) A nutritional supplement consisting essentially of an effective amount of hyaluronic acid, or a salt or digest thereof, and a food acceptable carrier, the nutritional supplement provided in an orally ingestible dosage form.

9. (Original) The nutritional supplement of claim 8 wherein the effective amount of hyaluronic acid is 1 to 6 mg.

10. (Original) The nutritional supplement of claim 8 wherein the orally ingestible dosage form is a capsule or gel seal.

11. (Original) A method for relieving joint pain or other discomforts associated with joint disorders in a warm-blooded vertebrate comprising the step of delivering to said vertebrate by oral ingestion a nutritional supplement consisting essentially of an effective amount of hyaluronic acid, or a salt or digest thereof.

12. (Original) The method of claim 11 wherein the effective amount of hyaluronic acid, or a salt or digest thereof, is from about 0.1 μg to about 400 μg/kg of body weight.

13. (Original) The method of claim 11 wherein the effective amount of hyaluronic acid, or a salt or digest thereof, is provided in liquid form.

REMARKS

I. Status of the Application

Claims 1-13 were filed in the original Application. In the Office Action, the Examiner:

(a) provisionally rejected claims 1-13 under the judicially created doctrine of obviousness-type double patenting;

(b) rejected claims 1-13 under 35 U.S.C. § 112, first paragraph, as allegedly not enabling a person skilled in the art to use the invention;

(c) rejected claim 9 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement; and

(d) rejected claims 1-13 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,924,273 to Pierce ("Pierce").

In this response, Applicant respectfully submits the following comments and Declaration of Prior Inventorship. Claims 1-13 also remain in the Application but are not amended. Applicant respectfully submits that the following remarks and the Declaration of Prior Inventorship incorporated herein traverse or overcome the Examiner's rejections to the Application.

II. No New Matter Is Introduced by Way of Amendment

Applicant respectfully submits that as there have been no amendments to the specification, drawings, and/or claims, no new matter has been introduced to the originally filed Application.

III. **The Nonstatutory Double Patenting Rejection Of Claims 1-13 Should Be Withdrawn**

In the Office Action, the Examiner rejected claims 1-13 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,607,745 to Leneau. Applicant submits herewith a terminal disclaimer to obviate the rejection of claims 1-13 under the judicially created doctrine of obviousness-type double patenting. Applicant encloses the payment of the terminal disclaimer fee of $130.00. For this reason, Applicant respectfully requests that the rejection of claims 1-13 under the judicially created doctrine of obviousness-type double patenting be withdrawn.

IV. **The Rejection of Claims 1-13 under 35 U.S.C. § 112, First Paragraph, as Allegedly Not Enabling one Skilled in the Art to Use the Invention is Overcome and Should be Withdrawn**

The Applicant respectfully submits that the rejection of claims 1-13 under 35 U.S.C. §112, first paragraph, as allegedly not enabling a person skilled in the art to use the invention, is overcome and should be withdrawn in view of the following comments.

The Examiner rejected claims 1-13 under 35 U.S.C. § 112, first paragraph, alleging that "the specification, while being enabling for joint disorders such as arthritis, osteoarthritis, rheumatoid arthritis, and fibromyalgia, does not reasonably provide enablement for all joint disorders." (Office Action, page 3). The Examiner further references additional specific joint disorders and alleges that the "specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims." (Office Action, page 3). Applicant respectfully submits that while it acknowledges that it did not name each and every possible joint disorder that may benefit from the ingestion of hyaluronic acid as disclosed in the Application, Applicant respectfully submits

that the number of joint disorders referenced within the Application most surely would enable one skilled in the art to use the invention commensurate in scope with these claims.

Specifically, and as acknowledged by the Examiner, Applicant disclosed several joint disorders in the Application, including the following:

- general arthritis/arthritic disorders (Paragraph 0002)
- osteoarthritis (Paragraph 0003)
- rheumatoid arthritis, both acute and chronic (Paragraph 0003)
- fibromyalgia (Paragraph 0002)
- general inflammatory skeletal and musculoskeletal conditions (Paragraph 0002)

Applicant respectfully submits that the disclosure of the aforementioned joint disorders in the Application most surely would enable one skilled in the art to use the invention commensurate in scope with these claims. "Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention." MPEP § 2164.01. "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). The focus is not only on "experimentation," but is on whether or not the experimentation is "undue." *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Applicant respectfully submits that no undue experimentation would be required by one skilled in the art in order to utilize the invention.

Applicant respectfully submits that while, for example, the Application does not disclose the specific joint disorder of carpal tunnel syndrome as referenced by the Examiner (Office Action, page 3), any experimentation to determine whether or not the oral ingestion of "a nutritional supplement consisting essentially of an effective amount of hyaluronic acid" (Application, claim 1) would relieve joint pain or other discomforts of carpal tunnel syndrome would not be considered "undue" experimentation. Applicant respectfully submits that such experimentation may require an oral dose of an effective amount of hyaluronic acid to a warm-blooded vertebrate with the specific joint disorder of carpal tunnel syndrome to determine whether or not the dose is effective in relieving the joint pain or other discomforts associated with that disorder. Applicant respectfully submits that at most, this would require some sort of experimentation, but that any such experimentation would not be "undue."

In addition, Applicant respectfully submits that no such experimentation may be required, as one skilled in the art may realize that one suffering from a particular joint disorder not enumerated in the Application (like carpal tunnel syndrome, for example) may benefit from the method and/or nutritional supplement disclosed in the Application. Applicant respectfully submits a Declaration from the inventor and one skilled in the art of joint disorders, Dr. Harry Leneau, affirmatively supporting the position that one skilled in the art may consider a treatment for one or more of the disclosed joint disorders (like arthritis, rheumatoid arthritis, and fibromyalgia) when attempting to treat one suffering from another joint disorder (like carpal tunnel syndrome, tendonitis, and bursitis). Accordingly, Applicant respectfully submits that the specification is properly enabling and that the rejection of claims 1-13 under 35 U.S.C. § 112, first paragraph, is overcome and should be withdrawn.

V. **The Rejection of Claim 9 under 35 U.S.C. § 112, First Paragraph, as Allegedly Failing to Comply with the Written Description Requirement is Overcome and Should be Withdrawn**

The Applicant respectfully submits that the rejection of claim 9 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement, is overcome and should be withdrawn in view of the following comments.

The Examiner rejected claim 9 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. (Office Action, page 3). The Examiner alleges that the effective amount of hyaluronic acid in claim 9 (1-6 mg) is not disclosed in the specification, acknowledging that the Application does disclose doses of 1-10 mg (Application, paragraph 0015) and 1-4 mg (Application, paragraph 0016). (Office Action, page 4).

Applicant respectfully disagrees with the Examiner's rejection of claim 9 under 35 U.S.C. §112, first paragraph, as the effective amount of hyaluronic acid claimed in claim 9 has sufficient support within the specification of the Application. Applicant respectfully submits that the Application states in Example 2 that "[e]ach patient received about 1 to about 6 mg of hyaluronic acid by oral ingestion administration of concentrate diluted into beverages or food." (Paragraph 0017). Accordingly, Applicant respectfully submits that there is sufficient support in the specification for the claimed range of 1-6 mg of hyaluronic acid in claim 9, and Applicant respectfully submits that the rejection of claim 9 under 35 U.S.C. § 112, first paragraph, is overcome and should be withdrawn.

VI. **The Rejection of Claims 1-13 under 35 U.S.C. § 102(e) as Allegedly Being Anticipated by Pierce is Overcome and Should be Withdrawn**

In the Office Action, the Examiner rejected claims 1-13 under 35 U.S.C. § 102(e) as allegedly being anticipated by Pierce. Applicant respectfully submits that the rejection of claims 1-13 is overcome and should be withdrawn because Applicant conceived, reduced to practice, and diligently completed the invention well before the priority date of Pierce. Submitted together herewith is a Declaration of Prior Inventorship in the United States (37 C.F.R. § 1.131) by the inventor for the Application, thereby eliminating Pierce as prior art to this Application. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection to claims 1-13 under 35 U.S.C. § 102(e).

CONCLUSION

For all the foregoing reasons, it is respectfully submitted that the Applicant has made a patentable contribution to the art and that this response places the Application in condition for allowance. Accordingly, favorable reconsideration and allowance of this Application is respectfully requested. In the event the Applicant has inadvertently overlooked the need for a payment of a fee or extension of time, the Applicant conditionally petitions therefor, and authorize any fee deficiency to be charged to deposit account 09-0007. When doing so, please reference the above-listed docket number.

Respectfully submitted,

ICE MILLER LLP

Mark C. Reichel
Registration No.: 53,509

ICE MILLER LLP
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Facsimile: (317) 592-5453

MCR/ldh
Enclosures: Transmittal Form (PTO/SB/21)
Terminal Disclaimer to Obviate a Double Patenting Rejection Over a "Prior" Patent
Declaration of Prior Inventorship in the United States (37 C.F.R. § 1.131)
Check No. 323455 in amount of $640.00
Return Postcard

PTO/SB/26 (09-06)
Approved for use through 03/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT

Docket Number (Optional)
P00903-US-01 (21934.0001)

In re Application of: LENEAU, Harry

Application No.: 10/629,880

Filed: July 29, 2003

For: INGESTION OF HYALURONIC ACID FOR IMPROVED JOINT HEALTH

The owner*, Leneau Holdings, LLC, of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term **prior patent** No. 6,607,745 as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said **prior patent** is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:

- expires for failure to pay a maintenance fee;
- is held unenforceable;
- is found invalid by a court of competent jurisdiction;
- is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
- has all claims canceled by a reexamination certificate;
- is reissued; or
- is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☑ The undersigned is an attorney or agent of record. Reg. No. 53,509

Signature — Date: 11/03/2006

11/08/2006 CNGUYEN2 00000031 10629880
02 FC:2814 65.00 OP

Mark C. Reichel
Typed or printed name

(317) 236-5882
Telephone Number

☑ Terminal disclaimer fee under 37 CFR 1.20(d) included.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re:	Invention:	INGESTION OF HYALURONIC ACID FOR IMPROVED JOINT HEALTH
	Inventors:	LENEAU, Harry
	Serial No.:	10/629,880
	Filed:	July 29, 2003
	Art Unit:	1615
	Examiner:	HAWES, Pili Asabi
	Confirmation No:	5579
	Our Docket No.:	P00903-US-01 (21934.0001)

DECLARATION OF PRIOR INVENTORSHIP IN THE UNITED STATES (37 C.F.R. § 1.131)

I, Harry Leneau, individually declare as follows:

1. I am the inventor of the subject matter described in the above-identified patent application.

2. Attached to this Declaration is a report (the "Report") entitled "ORAL HYALURONIC ACID (HA) FIELD STUDY FOR POSSIBLE EFFICACY" by Steven C. Allday, DVM, from November 5, 1999, regarding an arthritis evaluation of horses by orally administering hyaluronic acid. The Report contains information corresponding to the subject matter in the above-identified patent application.

3. Prior to the submission of the Report, I provided Dr. Allday with the hyaluronic acid and the instructions to perform the animal studies referenced within the Report.

4. The Report states that "[t]he HA utilized in this evaluation was according to specifics outlined by Amervet Labs Inc." I am the founder of Amervet Labs Inc.

5. The Report was submitted to me from Dr. Allday and was not publicly available prior to the time of filing the above-referenced patent application. Dr. Allday performed the animal studies at my request and direction, and the studies were performed for me by Dr. Allday in confidence.

6. Accordingly, the Report shows that the subject matter described in the above-identified patent application was conceived and reduced to practice at least by the date November 5, 1999, which is a date earlier than the effective date of U.S. Patent No. 6,924,273, namely October 3, 2000. Additional animal studies to determine efficacy and confirm dosing ranges were diligently pursued up to and after the date of filing U.S. Patent Application No. 09/860,426 on May 18, 2001, of which the above-identified application claims priority.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both (under Section 1001 of Title 18 of the United States Code), and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

INVENTOR:

Harry Leveau

Harry Leveau

11-3-2006

Date

ORAL HYALURONIC ACID (HA)

FIELD STUDY FOR POSSIBLE EFFICACY

S.C.Allday DVM

November 5, 1999

Methods: Horses with known arthritis problems were identified and evaluated for use in an arthritis evaluation using oral hyaluronic acid. The HA used in this evaluation was according to specifics outlined by Amervet Labs Inc. The HA utilized in this evaluation was molecular weight of greater 2.0 million Daltons. The amount given daily was started at 5mg per day. Clinical response was evaluated weekly with the two equine patients given a physical examination to determine lameness associated with known arthritic problems. These horses were jogged on asphalt and given scores varying from 1 to 5. 1 being slight noticeable lameness to 5 being non weight bearing. Both horses are retired show horses that have front fore feet shod every 5 weeks.

Observations: Both horses had long standing demonstrable lameness that have been clinically diagnosed via peripheral and intra-articular blocks as well as radiography to confirm the diagnosis. Both horses were kept in a paddock where they were visually monitored daily for normal health issues (normal behavior, food and water intake, injuries and other possible disease processes)

Weekly evaluations were very routine and simply involved a handler jogging each horse on asphalt and recording the degree of lameness. The only time either of these horses were removed from the weekly evaluations was when they had foot abscesses and the source of the lameness could not be determined. During those periods the horse was treated with non-steroidal anti-inflammatory medication (phenylbutazone) and the foot soaked in hot water and Epsom salts until the peripheral pulse was considered normal in that limb.

The initial dosage of 5mg was maintained for 42 days, 10 mg for 44 days, 20 mg for 28 days 40 mg for 34 days, 60 mg for 28 days and 75 mg for 27 days. All of the oral doses were maintained with increases for consecutive days even when a horse was excluded with treatment for a foot abscess.

Summary: The long process of treating and evaluating this method of administration did yield fairly demonstrable results to improve lameness but only when given much higher doses than originally proposed. Oral administration was much more convenient and much less troublesome than I.V. injections or intra-articular injections. Horses accepted the oral doses easily without resistance even when the volumes increased. (5mg/ml solution) Initial doses were 1ml/day and last doses were 15 mls/day.

Conclusions: Oral administration of hyaluronic acid solution appears to be an effective and highly convenient method of administration to relieve symptoms of osteo-arthritis. Further studies will be necessary with larger sample groups in order to provide adequate statistical data for proper analysis.

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,880	07/29/2003	Harry Leneau	29792-73218	5579

22446 7590 09/24/2007

ICE MILLER LLP
ONE AMERICAN SQUARE, SUITE 3100
INDIANAPOLIS, IN 46282-0200

EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
09/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/629,880	LENEAU, HARRY	
	Examiner	Art Unit	
	Aradhana Sasan	1615	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/29/03, 7/16/04, 12/20/04*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and declaration filed on 11/7/06 are acknowledged.

2. Claims 1-13 are included in the prosecution.

Information Disclosure Statement

3. The information disclosure statement filed 7/29/03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but all the information referred to therein has not been considered. Please see attached PTO-1449.

Response to Arguments

4. Rejection of claims 1-13 on the ground of nonstatutory obviousness-type double patenting over claims 1-7 of US 6,607,745

Applicant's filing of the terminal disclaimer (11/7/06) overcomes the rejection of claims 1-13 on the ground of nonstatutory obviousness-type double patenting over claims 1-7 of US 6,607,745.

5. Rejection of claims 1-13 under 35 USC § 112, first paragraph, enablement

Applicant's arguments with respect to the rejection of claims 1-13 under 35 USC § 112, first paragraph, as not providing enablement for all joint disorders, have been fully considered. Applicant argues that the number of joint disorders referenced within the application would enable one skilled in the art to use the invention commensurate in

scope with these claims and that no undue experimentation would be required to use the invention. Applicant's declaration regarding the treatment for one or more joint disorders when treating another joint disorder was found persuasive and the rejection of 5/4/06 has been withdrawn.

6. Rejection of claim 9 under 35 USC § 112, first paragraph, written description

Applicant's arguments with respect to the rejection of claim 9 under 35 USC § 112, first paragraph, as failing to comply with the written description requirement, have been fully considered and are found persuasive. The rejection of 5/4/06 has been withdrawn.

7. Rejection of claims 1-13 under 35 USC § 102(e) as being anticipated by Pierce (US 6,924,273)

8. Applicant's arguments and declaration of prior inventorship with respect to the rejection of claims 1-13 under 35 USC § 102(e) as being anticipated by Pierce (US 6,924,273) have been fully considered but they are not persuasive. Since applicant is claiming the same invention as Pierce, the declaration of prior inventorship is not sufficient to overcome the 35 USC § 102(e) rejection. See MPEP § 715.05.

Applicant failed to provide a detailed explanation as to why applicant will prevail on priority. See 37 CFR 41.202(a)(4), (a)(6), (d) and MPEP § 2304.02(c).

The rejection of 5/4/06 is maintained.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Pierce US 6924273.

Pierce teaches a method of treating or preventing osteoarthritis, joint inflammation and pain by administering to a mammal hyaluronic acid (col. 4, lines 46-55 and col. 5, lines 30-35). The reference teaches using 0.1-0.5 mg of hyaluronic acid per kg of body weight in the composition (col. 9, lines 34-39). The reference teaches the effective amount for canines range from 2-8 mg. The compositions can be in the form of a paste, gel, tablets, and capsules (col. 11, lines 59-60). Example discloses a hyaluronic composition that comprises water as the food acceptable carrier (col. 17, lines 1-15).

Conclusion

11. No claims are allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

PTO/SB/08A (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	10/629,880
Filing Date	July 29, 2003
First Named Inventor	LENEAU, Harry
Art Unit	1615
Examiner Name	PAGE, T.
Attorney Docket Number	p00903-us-01

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
/A.S./		WO 00/44367	08/03/2000	Brown, et al.		

Examiner Signature	/Aradhana Sasan/	Date Considered	08/09/2007

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.	SERIAL NO.
29792-73218	Unknown
APPLICANT: Harry Leneau.	
FILING DATE: July 29, 2003	GROUP: Unknown

U.S. PATENT DOCUMENTS

*Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
	BA						
	BB						
	BC						
	BD						
	BE						
	BF						
	BG						
	BH						
	BI						
	BJ						
	BK						

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation Yes No
	BL						
	BM						
	BN						
	BO						
	BP						

OTHER REFERENCES *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	BR	~~"Hyaluronic Acid", from website www.bioiberica.com/eng/imp/hyaluronic.htm~~
	BS	~~"Hyaluronic acid", from website www.medmedia.com/02/06.htm~~
	BT	~~"Hyaluronic Acid" from website uconnsportsmed.bchc.edu/hyaluronic_acid.htm~~
	BU	
	BV	
	BW	
	BX	
	BY	
	BZ	

Examiner	/Aradhana Sasan/	Date Considered	08/09/2007

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

BASED ON FORM PTO 1449

(INDS02 JTP 5984SDv)

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 29792-73218	SERIAL NO. Unknown
	APPLICANT Harry Leneau.	
	FILING DATE July 29, 2003	GROUP Unknown

U.S. PATENT DOCUMENTS

*Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if
/A.S./	AA	4,808,576	Feb. 28, 1989	Schpitz et al.			
/A.S./	AB	5,470,578	Nov. 28, 1995	Aoki et al.			
/A.S./	AC	5,633,003	May 27, 1997	Cantor			
/A.S./	AD	6,159,955	Dec. 12, 2000	Asculai et al.			
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation Yes No
	AL						
	AM						
	AN						
	AO						
	AP						

OTHER REFERENCES *(Including Author, Title, Date, Pertinent Pages, Etc.)*

/A.S./	AR	"Hyaluronan (Hyaluronic acid, Synvise, Hyalgan)" from website *www.midwestarthritis.com/html/hyaluronic_acid.htm*
	AS	~~Wen, Dennis Y., "Intra-articular Hyaluronic Acid Injections for Knee Osteoarthritis", *American Family Physician*, 60, 565-70, 572, (2000)~~
	AT	~~Marte, Jim, "Green Plaster, A Webpage Resource For Orthopaedic Technologists: Intra-Articular Hyaluronic~~ Acid Injections for Knee Osteoarthritis", from website *home.earthlink.net/~jim56/otchyal.htm*
	AU	~~"Arthritic Disorders", www.advanhealth.com/arthritis.htm~~
	AV	~~"Arthritic Disorders and Treatments", from website www.e.org/brarthdis.html~~
	AW	~~"Hillbrook Wellness Institute", from website www.hillbrookl.com~~
	AX	~~"Glucosamine and Chondroitin", from website~~ *chemistry.about.com/science/chemistry/library/weekly/aa120400a.htmi, (12/00)*
/A.S./	AY	"Fibromyalgia Basics - Symptoms, Treatments and Research", from website *www.fmnetnews.com/pages/basics.html*
	AZ	~~"Hyaluronic Acid (Hyaluronan)", from website www.apharma.it/site/html/hyaluronic.htm~~

Examiner	/Aradhana Sasan/	Date Considered	08/09/2007

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

BASED ON FORM PTO 1449

PTO/SB/08A (08-03)
Approved for use through 07/31/2005. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Complete if Known	
Application Number	10/629,880
Filing Date	July 29, 2003
First Named Inventor	LENEAU, H.
Art Unit	1615
Examiner Name	Page, T.
Attorney Docket Number	P00903US01

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/A.S./	DA	US- 4,303,676	12-02-1981	Balazs	
		US-			
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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]
/A.S./	DB	WO 97/25051	07-17-1997	Turley		
/A.S./	DC	WO 92/22585	12-23-1992	Gallina		
/A.S./	DD	JP9262057 (abstract)	10-07-1997	Jennal		

Examiner Signature	/Aradhana Sasan/	Date Considered	08/09/2007

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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November 26, 2007

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I hereby certify that this correspondence is being deposited with the United States Postal Services as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 26, 2007.

Linda Decker
Printed or typed Name of person signing certificate

Linda Decker
(Signature)

November 26, 2007
Date of Signature

Re:	Invention:	INGESTION OF HYALURONIC ACID FOR IMPROVED JOINT HEALTH
	Inventors:	LENEAU, Harry
	Serial No.:	10/629,880
	Filed:	July 29, 2003
	Art Unit:	1615
	Examiner:	SASAN, Aradhana
	Confirmation No:	5579
	Our Docket No.:	P00903-US-01 (21934.0001)

RESPONSE TO OFFICE ACTION

In response to the final Office Action mailed September 24, 2007 (the "Office Action"), Applicant files the present complete response (the "Response") within two months of the Office Action. The listing of claims starting on page 2 will replace all prior versions and listings of the claims in the above-referenced patent application (the "Application"). The Remarks begin on page 4 of this paper.

CLAIMS

I claim:

1. (Original) A method for relieving joint pain or other discomforts associated with joint disorders in a warm-blooded vertebrate comprising the step of delivering to said vertebrate by oral ingestion a nutritional supplement consisting essentially of an effective amount of hyaluronic acid, or a salt or digest thereof, and a food acceptable carrier, wherein the effective amount of hyaluronic acid, or a salt or digest thereof, is from about 0.1 μg to about 400 μg/kg of body weight.

2. (Original) The method of claim 1 further comprising the step of adding the hyaluronic acid, or a salt or digest thereof, to the carrier, and wherein the carrier comprises food or water.

3. (Original) The method of claim 1 wherein the nutritional supplement is provided in capsule form.

4. (Original) The method of claim 1 wherein the warm-blooded vertebrate is a human, or an equine, canine, or feline species.

5. (Original) The method of claim 1 wherein the joint pain is the result of an arthritic condition.

6. (Original) The method of claim 5 wherein the arthritic condition is selected from the group consisting of osteoarthritis and rheumatoid arthritis.

7. (Original) The method of claim 1 wherein the joint pain is the result of an inflammatory condition involving skeletal or musculoskeletal structures.

8. (Original) A nutritional supplement consisting essentially of an effective amount of hyaluronic acid, or a salt or digest thereof, and a food acceptable carrier, the nutritional supplement provided in an orally ingestible dosage form.

9. (Original) The nutritional supplement of claim 8, wherein the effective amount of hyaluronic acid is 1 to 6 mg.

10. (Original) The nutritional supplement of claim 8 wherein the orally ingestible dosage form is a capsule or gel seal.

11. (Cancelled)

12. (Currently amended) ~~The method of claim 11~~ A method for relieving joint pain or other discomforts associated with joint disorders in a warm-blooded vertebrate comprising the step of delivering to said vertebrate by oral ingestion a nutritional supplement consisting essentially of an effective amount of hyaluronic acid, or a salt or digest thereof, wherein the effective amount of hyaluronic acid, or a salt or digest thereof, is from about 0.1 μg to about 400 μg/kg of body weight.

13. (Currently amended) The method of claim [[11]] 12 wherein the effective amount of hyaluronic acid, or a salt or digest thereof, is provided in liquid form.

REMARKS

I. STATUS OF THE APPLICATION

Claims 1-13 were pending in the Application. In the Office Action, the Examiner:

(a) accepted Applicant's terminal disclaimer to overcome the rejection of claims 1-13 on the ground of nonstatutory obviousness-type double patenting over claims 1-7 of U.S. Patent No. 6,607,745;

(b) accepted Applicant's argument and withdrew the rejection of claims 1-13 under 35 U.S.C. § 112, first paragraph, as allegedly not enabling a person skilled in the art to use the invention;

(c) accepted Applicant's argument and withdrew the rejection of claim 9 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement;

(d) maintained the rejection of claims 1-13 under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 6,924,273 to Pierce ("Pierce").

In this response, Applicant respectfully submits the following comments and amendments to claims 11-13. Claims 1-10 remain in the Application but are not amended. Applicant respectfully submits that the following remarks herein traverse or overcome the Examiner's rejections to the Application.

II. NO NEW MATTER IS INTRODUCED BY WAY OF AMENDMENT

Applicant respectfully submits that no new matter has been added by amending claims 11-13. Specifically, the amendments to claim 12 were to place claim 12 in independent form by incorporating the content of independent claim 11. Accordingly, claim 11 has been cancelled. Claim 13 was also amended to depend from amended claim 12. Applicant respectfully submits

that the amendments are supported by the originally filed Application and do not add new matter. Accordingly, Applicant requests that the amendments be entered and that the Application proceed to allowance for the reasons provided herein.

III. THE REJECTION OF CLAIMS 1-13 UNDER 35 U.S.C. § 102(e) AS ALLEGEDLY BEING ANTICIPATED BY PIERCE IS OVERCOME AND SHOULD BE WITHDRAWN

In the Office Action, the Examiner maintained the rejection of claims 1-13 under 35 U.S.C. § 102(e) as allegedly being anticipated by Pierce. Applicant respectfully submits that the rejection of claims 1-13 is overcome and should be withdrawn because (a) the Application is not claiming the same invention as Pierce, (b) the claims of the Application and Pierce are patentably distinct, (c) the limitations contained within MPEP §§ 715.05 and 2304.02(c) and 37 C.F.R. §§ 41.202(a)(4), (a)(6), (d) do not apply to the present Application, and (d) Pierce does not constitute prior art to the present Application.

In the Office Action, the Examiner stated that "[s]ince applicant is claiming the same invention as Pierce, the declaration of prior inventorship is not sufficient to overcome the 35 USC §102(e) rejection. See MPEP § 715.05." Office Action, page 3. In addition, the Examiner stated that "Applicant failed to provide a detailed explanation as to why applicant will prevail on priority. See 37 CFR 41.202(a)(4), (a)(6), (d) and MPEP § 2304.02(c). Office Action, page 3. Applicant respectfully submits that these statements are inapplicable to the Applicant's declaration of prior inventorship dated November 3, 2006 (the "Declaration"), and as such, the Declaration is indeed sufficient to overcome the present rejection of claims 1-13 under 35 U.S.C. § 102(e).

A. THE LIMITATIONS OF MPEP § 715.05 DO NOT APPLY TO THE PRESENT APPLICATION AND THEREFORE APPLICANT'S DECLARATION IS EFFECTIVE TO OVERCOME THE 35 U.S.C. § 102(E) REJECTION

Applicant respectfully submits that the limitations of MPEP § 715.05 do not apply to the present application. MPEP §715.05 presently states the following in the opening paragraph:

> When the reference in question is a noncommonly owned U.S. patent or patent application publication ***claiming the same invention*** as applicant and its publication date is less than 1 year prior to the presentation of claims to that invention in the application being examined, applicant's remedy, if any, must be by way of 37 CFR 41.202 instead of 37 CFR 1.131.
> (emphasis added)

In addition, MPEP §715.05 states that "[a] 37 CFR 1.131 affidavit is ineffective to overcome a United States patent or patent application publication, not only where there is a verbatim correspondence between the claims of the application and of the patent, ***but also where there is no patentable distinction between the respective claims***." (citations omitted, emphasis added).

Applicant respectfully submits that because the pending Application is not claiming the same invention as Pierce, and because there is a patentable distinction between the claims of the Application and the claims of Pierce, the limitations of MPEP 715.05 do not apply to the Declaration, and the Declaration is effective to overcome the 35 U.S.C. § 102(e) rejection based upon Pierce.

1. THE LIMITATIONS OF MPEP § 715.05 DO NOT APPLY TO THE PRESENT APPLICATION BECAUSE THE PRESENT CLAIMS DO NOT CLAIM THE SAME INVENTION AS PIERCE

Applicant respectfully submits that because the pending Application is not claiming the same invention as Pierce, the limitations of MPEP 715.05 do not apply. Specifically, because the claims, as presently amended, do not claim the same invention as Pierce, the previously submitted Declaration is effective to overcome the maintained 35 U.S.C. § 102(e) rejection.

The claims of the Application, as presently amended, include claims for a method for relieving joint pain or other discomforts associated with joint disorders and claims for a nutritional supplement. Pierce includes nine (9) method claims (claims 20-28) and nineteen (19) composition claims (claims 1-19). Applicants respectfully submit that as will be demonstrated below, the claims of the present Application ***do not claim the same invention*** as claimed in Pierce.

THE METHOD CLAIMS

Applicant respectfully submits that the method claims of the present Application, as amended, ***do not claim the same invention*** as claimed in the method claims of Pierce.

Claims 20-28 of Pierce are the only method claims included within Pierce. Claim 20, the only independent method claim of Pierce, includes the following general elements:

a. "A method of treating osteoarthritis...[and other disorders]..., said method comprising..."
b. "...orally administering..."
c. "...to [a] mammal..."
d. "...a therapeutically effective amount..."
e. "...of the composition of claim 1."

Regarding method element (e) above, the composition of claim 1 of Pierce includes the following elements:

w. "An orally administrable Chondroprotective/Restorative composition..."
x. "...gel or paste form..."
y. "...an effective amount of hyaluronic acid or its pharmaceutically acceptable salts..."
z. "...a pharmaceutically acceptable gelling or pasting agent capable of forming a gel or a paste selected from the group consisting of hydroxypropyl methyl cellulose, hydroxymethyl cellulose, methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, cellulose acetate, ethyl cellulose, methyl hydroxy ethyl cellulose, hydroxy ethyl cellulose, cellulose gum carboxymethylcellulose, sodium carboxymethylcellulose and molasses."

Accordingly, Applicant respectfully submits that claim 20 of Pierce, considering that method element (e) above references the composition described in composition elements (w) through (z), effectively includes method elements (a) through (d) and composition elements (w) through (z).

The present Application contains nine (9) method claims as presently amended, namely claims 1-7 and 12-13. Claim 12, as amended, is objectively the method claim of the present Application with the broadest scope (the fewest elements). Applicant's claim 12 contains the following elements:

i. "A method for relieving joint pain or other discomforts associated with joint disorders..."
ii. "...in a warm blooded vertebrate..."
iii. "...comprising the step of delivering to said vertebrate by oral ingestion..."
iv. "...a nutritional supplement consisting essentially of an effective amount of hyaluronic acid, or a salt or digest thereof..."
v. "...wherein the effective amount of hyaluronic acid, or a salt or digest thereof, is from about 0.1 μg to about 400 μg/kg of body weight."

Applicant respectfully submits that claim 20 of Pierce, effectively including composition elements (w) through (z) of claim 1 of Pierce, ***does not claim the same invention*** as claimed in

Applicant's claim 12. Applicant respectfully submits the following list of differences between the two claims:

1. Composition element (x) of Pierce requires the composition to be in "gel or paste form." This element does not appear in Applicant's claim 12, which does not require the nutritional supplement referenced therein to be in "gel or paste form."

2. Composition element (z) of Pierce requires a "pharmaceutically acceptable gelling or pasting agent capable of forming a gel or a paste selected from the group consisting of hydroxypropyl methyl cellulose, hydroxymethyl cellulose, methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, cellulose acetate, ethyl cellulose, methyl hydroxy ethyl cellulose, hydroxy ethyl cellulose, cellulose gum carboxymethylcellulose, sodium carboxymethylcellulose and molasses." This element does not appear in Applicant's claim 12, which does not require the nutritional supplement referenced therein to include any type of "gelling or pasting agent."

3. Method element (v) of Applicant's claim 12 requires that "the effective amount of hyaluronic acid, or a salt or digest thereof, is from about 0.1 μg to about 400 μg/kg of body weight." Claim 20 of Pierce, even when considering the elements of claim 1 of Pierce, does not provide for any specific range of hyaluronic acid or its pharmaceutically acceptable salts.

Furthermore, Applicant respectfully submits that Applicant's claim 1 differs from Applicant's claim 12 as Applicant's claim 1 includes the delivery of a nutritional supplement "and a food acceptable carrier." Applicant respectfully submits that claim 20 of Pierce, even when considering the elements of claim 1 of Pierce, does not include the element or limitation of a composition "and a food acceptable carrier."

Applicant respectfully submits that as provided above, Applicant's method claims differ from the method claims of Pierce, and accordingly, Applicant's method claims do not claim the same invention as the method claims of Pierce.

THE COMPOSITION CLAIMS

Applicant respectfully submits that the composition claims of the present Application, as amended, ***do not claim the same invention*** as claimed in the composition claims of Pierce.

Claims 1-19 of Pierce are the only composition claims included within Pierce. Applicant respectfully submits that no composition claim of Pierce claims the same invention as claimed in any of Applicant's pending composition claims.

Applicant respectfully submits that none of the composition claims of Pierce (claims 1-19) need to be considered as relevant to the present inquiry ***as each claim requires effective amounts of additional ingredients not claimed in Applicant's composition claims***. Specifically, the following claims of Pierce require the inclusion of one or more additional supplements/ingredients not required in Applicant's composition claims:

Claim 1: requires, at a minimum, "a pharmaceutically acceptable gelling or pasting agent capable of forming a gel or paste", with the gelling or pasting agent "selected from the group consisting of hydroxypropyl methyl cellulose, hydroxymethyl cellulose, methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, cellulose acetate, ethyl cellulose, methyl hydroxy ethyl cellulose, hydroxy ethyl cellulose, cellulose gum carboxymethylcellulose, sodium carboxymethylcellulose and molasses."

Claim 2: requires nutritionally effective amounts of one or more vitamins or minerals provided therein

Claim 3: requires, at a minimum, "an effective amount of Glucosamine sulfate"

Claim 4: depends upon claim 3, and further requires nutritionally effective amounts of one or more vitamins or minerals provided therein

Claim 5: requires, at a minimum, "an effective amount of Chondroitin sulfate"

Claim 6: depends upon claim 5, and further requires nutritionally effective amounts of one or more vitamins or minerals provided therein

Claim 7: requires, at a minimum, "an effective amount of Glucosamine sulfate" and an effective amount of Chondroitin sulfate"

Claim 8: depends upon claim 7, and further requires nutritionally effective amounts of one or more vitamins or minerals provided therein

Claim 9: requires, at a minimum, "an effective amount of a therapeutic drug" aside from hyaluronic acid and "a pharmaceutically acceptable gelling or pasting agent capable of forming a gel or paste"

Claim 10: depends upon claim 9, and requires that the therapeutic drug be selected from a group consisting over 200 compounds provided therein

Claim 11: claims a composition "in paste form" and requires, at a minimum, "a sufficient amount of molasses to make a paste."

Claim 12: depends upon claim 11, and requires, at a minimum, glucosamine sulfate

Claim 13: depends upon claim 12, and further requires "nutritionally effective amounts of vitamins and minerals"

Claim 14: depends upon claim 11, and requires, at a minimum, chondroitin sulfate

Claim 15: requires, at a minimum, "a sufficient amount of carboxymethylcellulose or its sodium salt to make a gel"

Claim 16: depends upon claim 15, and further requires glucosamine sulfate

Claim 17: depends upon claim 15, and further requires chondroitin sulfate

Claim 18: depends upon claim 15, and further requires "nutritionally effective amounts of vitamins and minerals"

Claim 19: depends upon claim 18, and further requires chondroitin sulfate

Applicant's claims 8-10 are the only composition claims included within the present Application. Applicant's claim 8, the only independent composition claim pending in the Application, includes the following general elements:

A. "A nutritional supplement consisting essentially of..."
B. "..an effective amount of hyaluronic acid, or a salt or digest thereof..."
C. "...and a food acceptable carrier..."
D. "...the nutritional supplement provided in an orally ingestible dosage form."

Applicant's claim 9, depending upon claim 8, includes the following element:

E. "...wherein the effective amount of hyaluronic acid is 1 to 6 mg."

Applicant's claim 10, which also depends upon claim 8, includes the following element:

F. "...wherein the orally ingestible dosage form is a capsule or gel seal."

Applicant respectfully submits that composition claims 8-10 of the Application neither contain nor require the supplements/ingredients identified above with respect to composition claims 1-19 of Pierce. Furthermore, as shown immediately above and as similarly referenced with respect to Applicant's method claim 1, Applicant's composition claim 8 includes a nutritional supplement "and a food acceptable carrier." Applicant respectfully submits that composition claims 1-19 of Pierce do not include the element or limitation of a composition "and a food acceptable carrier" as claimed in Applicant's composition claim 8.

Accordingly, Applicant respectfully submits that as provided above, Applicant's composition claims differ from the composition claims of Pierce, and accordingly, Applicant's composition claims do not claim the same invention as the composition claims of Pierce.

2. THE LIMITATIONS OF MPEP § 715.05 DO NOT APPLY TO THE PRESENT APPLICATION BECAUSE THERE IS A PATENTABLE DISTINCTION BETWEEN THE CLAIMS OF THE APPLICATION AND THE CLAIMS OF PIERCE

Applicant respectfully submits that because the claims of the Application are patently distinct from the claims of Pierce, the limitations of MPEP 715.05 do not apply. Specifically,

because the claims of the Application, as presently amended, are patently distinct from the claims of Pierce, the previously submitted Declaration is effective to overcome the maintained 35 U.S.C. § 102(e).

Applicant respectfully submits that in a similar fashion as described above with respect to the method and composition claims of the present Application and Pierce not claiming the same invention, those claims are also patently distinct from one another.

For example, the only independent method claim of Pierce (claim 20) claims a method of treating osteoarthritis and other disorders using the composition of claim 1 of Pierce. This method claim is patently distinct from the broadest method claim of the present Application (claim 12, as amended) as (1) Pierce requires the composition to be in "gel or paste form" which is not required by Applicant's claim 12, (2) Pierce requires a "pharmaceutically acceptable gelling or pasting agent capable of forming a gel or paste", with the gelling or pasting agent "selected from the group consisting of hydroxypropyl methyl cellulose, hydroxymethyl cellulose, methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, cellulose acetate, ethyl cellulose, methyl hydroxy ethyl cellulose, hydroxy ethyl cellulose, cellulose gum carboxymethylcellulose, sodium carboxymethylcellulose and molasses" which is not required by Applicant's claim 12, and (3) Applicant's claim 12 requires "the effective amount of hyaluronic acid, or a salt or digest thereof, is from about 0.1 μg to about 400 μg/kg of body weight", while claim 20 of Pierce, even when considering the elements of claim 1 of Pierce, does not provide for any specific range of hyaluronic acid or its pharmaceutically acceptable salts. As is clearly shown by these exemplary comparisons, the method claims of the present Application are patentably distinct from the method claims of Pierce.

A similar conclusion can be made with respect to the composition claims. As referenced above, each of claims 1-19 of Pierce requires at least one additional supplement/ingredient than is claimed in Applicant's composition claims 8-10. By way of example, (1) claim 1 of Pierce requires "a pharmaceutically acceptable gelling or pasting agent capable of forming a gel or paste", (2) claims 2, 4, 6, 8, 13, and 18 of Pierce require "vitamins and minerals", (3) claims 3, 7, 12, and 16 of Pierce require glucosamine sulfate, and (4) claims 5, 7, 14, 17 and 19 of Pierce require chondroitin sulfate, each of which is not claimed or required by Applicant's composition claims 8-10. As is also clearly shown by these exemplary comparisons, the composition claims of the present Application are patentably distinct from the composition claims of Pierce.

Applicant respectfully submits that in addition to the foregoing, p*rima facie* evidence of Applicant's conclusion can be found when reviewing the prosecution history of Pierce. During the prosecution of Pierce, Examiner Devesh Khare performed a PLUS search on October 22, 2004. The date of this search is indicated on the Search Notes document for the Pierce application, a copy of which is enclosed for reference.

The PLUS search performed by Examiner Khare identified fifty (50) patent references, some of which are duplicate results. A copy of the PLUS search results for the Pierce application is enclosed with this Response. One of the patents identified by the PLUS search was U.S. Patent No. 6,607,745 to Leneau et al. (the "'745 Patent") (indicated by the arrow written in by counsel for Applicant), which is significant as the '745 Patent is the parent patent to the present Application. The present Application is a continuation-in-part of the application resulting in the '745 Patent.

Applicant respectfully submits that although the '745 Patent was identified by Examiner Khare, the next formal action taken by Examiner Khare, aside from the submission of interview summary documents, was the submission of a Notice of Allowability and a Notice of Allowance and Fees Due for the Pierce patent application. The '745 Patent was never referenced by Examiner Khare in a Notice of References Cited accompanying any office action issued during the prosecution of Pierce, and accordingly, Applicant respectfully submits that the identification of the '745 Patent in the PLUS search and the lack of citation of that reference by Examiner Khare in any office action of Notice of References Cited is *prima facie* evidence that the '745 Patent was patently distinct from Pierce.

In an office action dated May 4, 2006, the Examiner of the present Application presented an rejection of claims 1-13 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,607,745. In that rejection, the Examiner noted that the conflicting claims were "not identical", but that they were "not patentably distinct from each other" for the reasons provided therein. In response, Applicant submitted a terminal disclaimer along with the response to the May 4, 2006, office action, to obviate the rejection of claims 1-13.

Applicant respectfully submits that as the claims of the present Application were deemed to be "not patentably distinct" from claims 1-7 of the '745 Patent, and because Applicant filed a terminal disclaimer that was accepted by the Examiner, the claims of the present Application should be viewed in a similar fashion as were the claims of the '745 Patent as reviewed by Examiner Khare during the prosecution of Pierce. Specifically, Applicant respectfully submits that if the claims of the '745 Patent were not deemed to be material to the prosecution of Pierce,

and because the Examiner of the present Application has stated that specific claims of the '745 Patent are "not patentably distinct" from the claims of the present Application, the claims of the present Application are patentably distinct from the claims of Pierce.

Accordingly, Applicant respectfully submits that because the pending Application is not claiming the same invention as Pierce, and because there is a patentable distinction between the claims of the Application and the claims of Pierce, the limitations of MPEP 715.05 do not apply to the previously submitted Declaration, and the Declaration is effective to overcome the 35 U.S.C. § 102(e) rejection based upon Pierce. Accordingly, Applicant respectfully requests that the Examiner withdraw the rejection to claims 1-13 under 35 U.S.C. § 102(e) and allow claims 1-10 and 12-13 to proceed to allowance.

B. APPLICANT IS NOT CLAIMING THE SAME INVENTION AS PIERCE, AND AS SUCH, 37 C.F.R. §§ 41.202(a)(4), (a)(6), (d) AND MPEP § 2304.02(c) DO NOT APPLY TO THE PRESENT APPLICATION

Applicant respectfully submits that because the Application does not claim the same invention as Pierce, the limitations of 37 C.F.R. §§ 41.202(a)(4), (a)(6), (d) and MPEP § 2304.02(c) do not apply to the present Application.

In the Office Action, the Examiner stated that "Applicant failed to provide a detailed explanation as to why applicant will prevail on priority. See 37 CFR 41.202(a)(4), (a)(6), (d) and MPEP § 2304.02(c)." Office Action, page 3. Applicant respectfully submits that 37 C.F.R. § 41.202 ("Suggesting an interference.") and MPEP § 2304.02(c) ("Explaining Priority – 2300 Interference Proceedings") do not Apply to the present Application because there is a patentable distinction between the claims of the Application and the claims of Pierce as described above.

MPEP §2304.02(c) begins with a recitation of sections (a)(4), (a)(6) and (d)(2) of 37 C.F.R. §41.202, which lists the requirements an applicant must meet when suggesting an interference with another application or patent. Applicant respectfully submits that these sections, and the remaining sections of 37 C.F.R. §41.202 not cited within MPEP §2304.02(c) do not apply as Applicant is ***not*** suggesting an interference. Applicant respectfully submits that such a suggestion is not being made because, as is shown in Section **III(A)** above, the pending Application is not claiming the same invention as Pierce and because the pending claims of the Application are patentably distinct from the claims of Pierce. Accordingly, Applicant respectfully requests that any requirement to provide such a suggestion within the Office Action be withdrawn.

C. PIERCE DOES NOT CONSTITUTE PRIOR ART TO THE PRESENT APPLICATION AS THE DISCLOSURE OF THE PROVISIONAL APPLICATION FOR WHICH PIERCE CLAIMS PRIORITY DID NOT SUFFICIENTLY ENABLE THE PIERCE NON-PROVISIONAL PATENT APPLICATION

Applicant respectfully submits that notwithstanding the foregoing, Pierce does not qualify as prior art to the present Application. Specifically, the provisional patent application for which Pierce claims priority did not sufficiently enable the disclosure of the non-provisional Pierce application, and as such, the effective date of Pierce for purposes of its potential applicability to the present analysis prohibits Pierce from constituting prior art to the present Application.

1. THE PROCEDURAL HISTORY OF THE PIERCE APPLICATIONS

On October 3, 2000, the attorney for inventor Scott Pierce, John F. Dolan, filed U.S. Provisional Application No. 60/237,838, entitled "CHONDROPROTECTIVE/RESTORATIVE COMPOSITIONS AND METHODS THEREOF" (the "'838 Application"). On October 2, 2001, another attorney for Scott Pierce, Isaac A. Angres, filed U.S. Nonprovisional Patent Application No. 09/967,977, entitled "CHONDROPROTECTIVE/RESTORATIVE COMPOSITIONS AND METHODS THEREOF" (the "'977 Application"), claiming priority back to U.S. Provisional Application No. 60/237,838. U.S. Nonprovisional Patent Application No. 09/967,977 eventually issued as U.S. Patent No. 6,924,273 on August 2, 2005.

2. THE PROCEDURAL HISTORY OF THE LENEAU APPLICATIONS

On May 18, 2001, the attorney for inventor Harry Leneau, Jill Powlick of Barnes & Thornburg, filed U.S. Nonprovisional Application No. 09/860,425, entitled "INGESTION OF HYALURONIC ACID FOR IMPROVED JOINT FUNCTION AND HEALTH" (the "'425 Application"). The '425 Application eventually issued as U.S. Patent No. 6,607,745 on August 19, 2003. Prior to the issuance of the '745 Patent, the same attorney for inventor Harry Leneau filed a continuation-in-part application, namely U.S. Nonprovisional Application No. 10/629,880, entitled "INGESTION OF HYALURONIC ACID FOR IMPROVED JOINT FUNCTION AND HEALTH" (the "'880 Application"). The '880 Application claimed priority back to the '425 Application.

3. THE "INVENTION" OF THE '838 APPLICATION IS CLEARLY A COMPOSITION CONTAINING GLUCOSAMINE SULFATE, CHONDROITIN SULFATE, AND HYALURONIC ACID, AND NOT HYALURONIC ACID ALONE

Applicant respectfully submits that the "invention" disclosed by the Pierce '838 Application is clearly a composition containing glucosamine sulfate, chondroitin sulfate, and hyaluronic acid, and not a composition containing hyaluronic acid alone. The '838 Application, filed on October 3, 2000, disclosed a composition called "Chondrogen EQ" which was allegedly "the most unique chondroprotective / restorative agent available." '838 Application, page 1. The '838 Application, as shown by numerous references therein, makes it clear what the "invention" was within the '838 Application:

- "***The present invention***, which goes by the name Chondrogen EQ, was initially formulated ..." (emphasis added). '838 Application, page 1.
- "This highly palatable formulation is the first ***to combine high levels of Glucosamine sulfate (GS) with Chondroitin sulfate (CS) and Hyaluronic Acid (HA)*** in an easy to absorb, low molecular weight formula." (emphasis added) '838 Application, page 1.
- "***The present invention, with it's unique combination of GS, CS, and HA*** ..." (emphasis added). '838 Application, page 1.
- "As previously explained, ***the present invention comprises a highly palatable formulation, which is the first to combine high levels of Glucosamine sulfate (GS) with Chondroitin sulfate (CS) and Hyaluronic Acid (HA)*** ..." (emphasis added). '838 Application, page 3.
- "There is a beneficial effect when ***Glucosamine sulfate, Chondroitin sulfate, and Hyaluronic acid*** are administered orally. Generally, the oral administration of embodiments ***of the present composition has a quicker clinical response than is produced when each component of the composition is given individually. A significant difference*** is an acute or a rapid relied in joint pain inflammation and swelling achieved by oral administration of the composition." (emphasis added) '838 Application, pages 4-5.

- "Another benefit is that ***embodiments of the present invention, with it's high dose of Glucosamine sulfate, Hyaluronic acid, and Chondroitin sulfate***, appears to have a synergistic effect which hastens the clinical response." (emphasis added) '838 Application, page 5.

- "***One embodiment of the present invention is a unique formulation that combines Glucosamine sulfate, Chondroitin sulfate, and Hyaluronic acid into a paste formulation*** ..." (emphasis added). '838 Application, page 5.

- "Early clinical trials have shown that ***when the three products are combined***, they have a synergistic effect." (emphasis added) '838 Application, pages 5-6.

- "***Embodiments of the present invention possess the following advantages***: ... 2) ***Only combination of GS, CS, HA in a paste formulation*** ..." (emphasis added). '838 Application, page 6.

- "Because of their chemical similarities and the clinical reports of improvement of synovitis, ***HA has a synergistic effect with GS and CS when given orally***." ..." (emphasis added). '838 Application, page 9.

As is shown by these statements within the '838 Application, it is clear that the "invention" of the '838 Application is a combination of Glucosamine sulfate (GS), Chondroitin sulfate (CS) and Hyaluronic Acid (HA). Additional support for this conclusion can be found in the only two exemplary formulations provided in the '838 Application:

- Page 7: Embodiment comprising 46.03% Glucosamine sulfate, 4.60% Chondroitin sulfate, and 0.18% Sodium hyaluronate. In this embodiment, of the 50.81% (46.03% + 4.60% + 0.18%) combined active ingredients, only 0.35% (0.18%/50.81%) of the total active ingredients is sodium hyaluronate (the sodium salt of hyaluronic acid).

- Page 11 (unnumbered – page appearing after numbered page 10): Chondrogen EQ formulation comprising 36% Glucosamine sulfate, 4% Chondroitin sulfate, and 0.144% Sodium hyaluronate. In this embodiment, of the 40.144% (36% + 4% + 0.144%) combined active ingredients, only 0.36% (0.144%/40.144%) of the total active ingredients is sodium hyaluronate (the sodium salt of hyaluronic acid).

As is clearly shown, these two formulations only contain a very minor fraction (0.18% and 0.144%, respectively), of sodium hyaluronate as compared to the remaining ingredients.

When viewing the three named active ingredients of the "invention" of the '838 Application (namely glucosamine sulfate, chondroitin sulfate and Hyaluronic Acid), sodium hyaluronate only comprises 0.35% and 0.36%, respectively, of those two formulations. In the first formulation, for example, the weight ratio to the largest active ingredient (glucosamine sulfate) to sodium hyaluronate is over 255 to 1. In the second formulation, the weight ratio of glucosamine sulfate to sodium hyaluronate is also very high (250 to 1).

4. **THE '838 APPLICATION INTRODUCED, BUT DID NOT ENABLE, AN ORALLY ADMINISTRABLE COMPOSITION CONTAINING AN EFFECTIVE AMOUNT OF HYALURONIC ACID WITHOUT ALSO CONTAINING GLUCOSAMINE SULFATE AND CHONDROITIN SULFATE**

Applicant respectfully submits that the '838 Application introduced, but did not enable, an orally administrable composition containing an effective amount of hyaluronic acid without also containing glucosamine sulfate and chondroitin sulfate. Applicant acknowledges that the '838 Application does discuss the concept of oral administration of hyaluronic acid ("HA"), but Applicant respectfully submits that the introduction of this concept within the '838 Application included no evidence whatsoever to support the conclusions made therein. For example, page 5 of the '838 Application states the following:

> Another benefit received is that of oral preparation and administration of HA given, for example, in the equine in any formulation. The administration of the HA composition orally and having a clinical effect eliminates more evasive procedures.

In addition, page 9 of the '838 Application states the following:

> Clinically, responses are seen in 7 to 10 days vs three to four weeks or not at all when GS and CS are given without HA. Therefore, we have seen a dramatic decrease in synovitis when HA is combined with GS and CS. ***This leads us to***

> ***conclude that HA is absorbed orally and effective*** either ***alone*** or in combination with GS and CS. Therefore, an additional embodiment of the invention comprises a composition including HA and any acceptable carrier, such as the paste formulation disclosed herein and any other liquid, powder, gel or similar type carrier. (emphasis added).

Applicant respectfully submits that although the '838 Application states that "an additional embodiment of the invention comprises a composition including HA and any acceptable carrier", this statement contains no support from any other portion of the '838 Application and actually contradicts other statements in the application. This particular statement follows the prior two sentences in the '838 Application which state (in summary) that that clinical responses are seen when GS and CS are provided ***without HA***, and that a dramatic decrease in synovitis is seen ***when HA is combined with GS and CS***. As the '838 Application clearly discloses and intends to focus on an orally administrable composition containing GS, CS, and HA, a conclusion that the oral administration of HA alone without any evidence in support and that contradicts other statements within the same application, is clearly not enabled.

5. THE ONLY SUPPORT WITHIN THE PIERCE APPLICATIONS FOR AN ORALLY ADMINISTRABLE COMPOSITION CONTAINING AN EFFECTIVE AMOUNT OF HYALURONIC ACID WITHOUT GLUCOSAMINE SULFATE AND CHONDROITIN SULFATE APPEARED WITHIN THE '977 APPLICATION AND NOT THE '838 APPLICATION

Applicant respectfully submits that the only support within the Pierce applications for an orally administrable composition containing an effective amount of hyaluronic acid without glucosamine sulfate and chondroitin sulfate appeared within the '977 Application and not the '838 Application. As discussed in Section III(C)(4) above, the '838 Application introduced, but

provided no support for, an orally administrable composition containing an effective amount of hyaluronic acid without also containing glucosamine sulfate and chondroitin sulfate.

Applicant respectfully submits that support for such a product was first introduced in the on page 10 of the '977 Application. Starting on page 10, the '838 Application discusses the treatment of ten horses with an oral gel and provides data regarding the same on Tables 1 and 2 appearing on pages 12-13. By way of example, the "TREATED HORSES" section of Table 2 shows that horses 101, 105, 106, and 109 "Improved" during treatment using the hyaluronic acid gel.

Applicant respectfully submits that this data, first appearing in the '977 Application, is the first time the concept of an "effective" orally administrable composition containing hyaluronic acid and not containing glucosamine sulfate and chondroitin sulfate was enabled in either of the Pierce applications.

6. BECAUSE THE '838 APPLICATION DID NOT ENABLE AN ORALLY ADMINISTRABLE COMPOSITION CONTAINING AN EFFECTIVE AMOUNT OF HYALURONIC ACID WITHOUT GLUCOSAMINE SULFATE AND CHONDROITIN SULFATE, PIERCE IS NOT PRIOR ART WITH RESPECT TO THE PRESENT APPLICATION

Applicant respectfully submits that because the '838 Application did not enable an orally administrable composition containing an effective amount of hyaluronic acid without glucosamine sulfate and chondroitin sulfate, Pierce is not prior art with respect to the present Application.

Applicant respectfully submits that the parent application to the present Application, namely the '425 Application, was filed on May 18, 2001. Pierce's provisional application (the

'838 Application) was filed on October 3, 2000, approximately 7 ½ months prior to the filing of the '425 Application. Pierce then converted the '838 Application to the '977 Application on October 2, 2001, approximately 4 ½ months after Leneau filed the parent application (the '425 Application) to the present Application (the '880 Application).

Applicant respectfully submits that as pertaining to any orally administrable composition which may be disclosed within either of the Pierce applications that contains hyaluronic acid but not glucosamine sulfate or chondroitin sulfate, the '977 Application, and not the '838 Application, provides data enabling such a composition. Accordingly, and because the '977 Application was filed ***after*** the parent application (the '425 Application) for which the present Application (the '425 Application) claims priority, Pierce cannot be considered prior art with respect to such a composition. Accordingly, Applicant respectfully submits that the Pierce patent is not prior art to the present Application, and as such, Applicant respectfully requests that the Examiner withdraw the rejection to claims 1-13 under 35 U.S.C. § 102(e) and allow claims 1-10 and 12-13 to proceed to allowance.

IV. ADVISORY ACTION REQUESTED

Applicant respectfully submits that this Response is being effectively filed within two months of the mailing of the final Office Action. Accordingly, Applicant respectfully requests an Advisory Action from the Examiner stating that the present Application is in a condition for allowance. Should the Examiner recognize any matters of form that the Examiner can change without authorization from Applicant (under MPEP § 1302.04), Applicant respectfully requests

that such changes be made prior to the issuance of the Advisory Action acknowledging that the Application is in a condition for allowance.

CONCLUSION

For all the foregoing reasons, it is respectfully submitted that the Applicant has made a patentable contribution to the art and that this response places the Application in condition for allowance. Accordingly, favorable reconsideration and allowance of this Application is respectfully requested. In the event the Applicant has inadvertently overlooked the need for a payment of a fee or extension of time, the Applicant conditionally petitions therefor, and authorize any fee deficiency to be charged to deposit account 09-0007. When doing so, please reference the above-listed docket number.

Respectfully submitted,

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MCR
Enclosures: Search Notes for U.S. Application No. 09/967,977
PLUS Results for U.S. Application No. 09/967,977
Return Postcard

PLUS Search Results for S/N 09967977, Searched October 22, 2004

The Patent Linguistics Utility System (PLUS) is a USPTO automated search system for U.S. Patents from 1971 to the present. PLUS is a query-by-example search system which produces a list of patents that are most closely related linguistically to the application searched. This search was prepared by the staff of the Scientific and Technical Information Center, SIRA.

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Search Notes

Application No.	Applicant(s)	
09/967,977	PIERCE, SCOTT W.	
Examiner	**Art Unit**	
Devesh Khare	1623	

SEARCHED

Class	Subclass	Date	Examiner
514	54, 62, 2, 56		
424	423, 134.1,		
	450, 484,		
	756, 499,		
	548, 639,		
	486, 488.		
536	21, 54 18.7,		
	55.1, 55.2	10/22/04	DK

INTERFERENCE SEARCHED

Class	Subclass	Date	Examiner
514	54, 62 2, 56		
424	423, 134.1, 450,		
	548 639,		
536	21, 54, 18.7, 55.1.	10/22/04	DK

SEARCH NOTES (INCLUDING SEARCH STRATEGY)

	DATE	EXMR
EAST Search	9/5/03	DK
	10/22/04	DK
PLUS Search	10/22/04	DK.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,880	07/29/2003	Harry Leneau	29792-73218	5579

22446 7590 01/30/2008

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EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
01/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/629,880	LENEAU, HARRY	
	Examiner	Art Unit	
	Aradhana Sasan	1615	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 November 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on ____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: ____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): ____
6. ☐ Newly proposed or amended claim(s) ____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: ____
   Claim(s) objected to: ____
   Claim(s) rejected: *1-10 and 12-13*.
   Claim(s) withdrawn from consideration: ____

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: ____

Continuation of 11. does NOT place the application in condition for allowance because: Applicant's arguments regarding the rejection of claims 1-13 under 35 U.S.C. § 102(e) as being anticipated by Pierce have been fully considered but are not found persuasive. Instant claim 1 does not have closed language, it has the open language of "comprising". Therefore, there is not patentable distinction between instant claims and the invention disclosed by Pierce. Amended claim 12 also has the open language of "comprising the step" which leads to the same invention disclosed by Pierce. In claim 27, Pierce provides a "therapeutically effective amount of sodium hyaluronate is in the range of 10mg to 2000mg". Instant claim 12 recites an effective amount of hyaluronic acid from about 0.1 micrograms to about 400 micrograms per kg of body weight. Therefore, if 100Kg of body weight is used, the effective amount of hyaluronic acid is 40mg, which is within the range disclosed by Pierce. Applicant's arguments regarding the lack of citing the reference 6,607,745 during the prosecution of the Pierce patent are not found persuasive because they pertain to a different case and are not relevant to the present case.

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

ICEMILLER LLP
LEGAL COUNSEL

February 29, 2008

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

via EFS-Web

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I hereby certify that this paper or fee is being transmitted electronically to the Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, through the EFS-Web Filing System, on February 29, 2008.

MARK REICHEL
Printed or typed Name of person signing certificate

(Signature)

02-29-2008
Date of Signature

Re:	Invention:	INGESTION OF HYALURONIC ACID FOR IMPROVED JOINT HEALTH
	Inventors:	LENEAU, Harry
	Serial No.:	10/629,880
	Filed:	July 29, 2003
	Art Unit:	1615
	Examiner:	WOODWARD, Michael P. (Supervisory)
	Confirmation No:	5579
	Our Docket No.:	P00903-US-01 (21934.0001)

AMENDMENT AFTER FINAL TO PLACE THE APPLICATION IN A CONDITION FOR ALLOWANCE

In response to the Advisory Action mailed January 30, 2008 (the "Advisory Action") and Applicant's subsequent teleconference with Supervisory Patent Examiner Michael P. Woodward (the "Examiner"), Applicant files the present Amendment After Final to Place the Application in a Condition for Allowance (the "Amendment After Final") within one month of the date of mailing the Advisory Action. The listing of claims starting on page 2 will replace all prior versions and listings of the claims in the above-referenced patent application (the "Application"). The Remarks begin on page 4 of this paper.

CLAIMS

I claim:

1. (Currently amended) A method for relieving joint pain or other discomforts associated with joint disorders in a warm-blooded vertebrate ~~comprising~~ consisting of the step of delivering to said vertebrate by oral ingestion a nutritional supplement consisting essentially of an effective amount of hyaluronic acid, or a salt or digest thereof, and a food acceptable carrier, wherein the effective amount of hyaluronic acid, or a salt or digest thereof, is from about 0.1 μg to about 400 μg/kg of body weight.

2. (Cancelled)

3. (Original) The method of claim 1 wherein the nutritional supplement is provided in capsule form.

4. (Original) The method of claim 1 wherein the warm-blooded vertebrate is a human, or an equine, canine, or feline species.

5. (Original) The method of claim 1 wherein the joint pain is the result of an arthritic condition.

6. (Original) The method of claim 5 wherein the arthritic condition is selected from the group consisting of osteoarthritis and rheumatoid arthritis.

7. (Original) The method of claim 1 wherein the joint pain is the result of an inflammatory condition involving skeletal or musculoskeletal structures.

8. (Original) A nutritional supplement consisting essentially of an effective amount of hyaluronic acid, or a salt or digest thereof, and a food acceptable carrier, the nutritional supplement provided in an orally ingestible dosage form.

9. (Original) The nutritional supplement of claim 8, wherein the effective amount of hyaluronic acid is 1 to 6 mg.

10. (Original) The nutritional supplement of claim 8 wherein the orally ingestible dosage form is a capsule or gel seal.

11. (Cancelled)

12. (Cancelled)

13. (Currently amended) The method of claim [[12]] 1 wherein the effective amount of hyaluronic acid, or a salt or digest thereof, is provided in liquid form.

REMARKS

I. STATUS OF THE APPLICATION

Claims 1-10, 12 and 13 were pending in the Application. In the Advisory Action, the Examiner:

(a) rejected claims 1 and 12 as containing open-ended language; and

(b) rejected Applicant's argument regarding the lack of citing the reference 6,607,745 during the prosecution of the Pierce patent.

In this response, Applicant respectfully submits the following comments and amendments to claims 1, 2, 12, and 13. Applicant respectfully submits that the following amendments and remarks herein place the remaining claims within the Application in a condition for allowance.

II. ACKNOWLEDGEMENT OF TELECONFERENCE WITH THE EXAMINER

Applicant would like to thank Examiner Woodward for his time on February 28, 2008, to discuss the claims of the Application. Applicant hereby amends claims 1 and 13 and cancels claim 12 as discussed during that teleconference, and also cancels claim 2.

III. NO NEW MATTER IS INTRODUCED BY WAY OF AMENDMENT

Applicant respectfully submits that no new matter has been added by amending claims 1, 2, 12, and 13. Specifically, the amendment to claim 1 changes the "open-ended" language to "closed-ended" language consistent with the Examiner's comments in the Advisory Action and during the teleconference of February 28, 2008. Claim 2 has been cancelled by Applicant as a result of amending claim 1. Claim 12 has been cancelled by Applicant to facilitate allowance of

the present Application. Claim 13 has been amended to now depend from claim 1. Applicant respectfully submits that the amendments are supported by the originally filed Application and do not add new matter. Accordingly, Applicant respectfully requests that the amendments be entered so that the Application may proceed to allowance.

IV. PETITION FOR AN EXTENSION OF TIME

Applicant respectfully submits the present Amendment After Final within one-month of the date of mailing of the Advisory Action. As such, and in accordance with the calculations provided within MPEP § 706.07(f), as the Advisory Action was mailed after the end of the shortened statutory period of three-months after the date of mailing the final office action, the extension of time fee is calculated from the mailing date of the Advisory Action. Accordingly, Applicant hereby petitions for a one-month extension of time for the submission of the present Amendment After Final, and submits payment in the amount of $60.00 under 37 C.F.R. § 1.17(a)(1) along with the electronic submission of the present Amendment After Final.

CONCLUSION

For all the foregoing reasons, it is respectfully submitted that the Applicant has made a patentable contribution to the art and that this Amendment After Final places the Application in condition for allowance. Accordingly, favorable reconsideration and allowance of this Application is respectfully requested. In the event the Applicant has inadvertently overlooked the need for an additional payment of a fee or extension of time, the Applicant conditionally petitions therefor, and authorize any fee deficiency to be charged to deposit account 09-0007. When doing so, please reference the above-listed docket number.

Respectfully submitted,

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,880	07/29/2003	Harry Leneau	29792-73218	5579

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EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
03/31/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/629,880	**Applicant(s)** LENEAU, HARRY	
	Examiner ARADHANA SASAN	**Art Unit** 1615	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 29 February 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,3-10 and 13*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Michael P Woodward/
Supervisory Patent Examiner, Art Unit 1615

Continuation of 11. does NOT place the application in condition for allowance because: Upon analysis of the claims, the first embodiment of the Pierce patent (US 6,924,273) anticipates instant claims. In particular, instant claim 1 which recites "a method for relieving joint pain ... in a warm-blooded vertebrate consisting of the step of delivering to said vertebrate by oral ingestion a nutritional supplement consisting essentially of an effective amount of hyaluronic acid..." is anticipated by the embodiment that provides "viscosupplementation of joints by oral administration of sodium hyaluronate (HA) to mammals and more in particular to racing thoroughbreds" (Col. 5, lines 43-55). The limitation of an effective amount of hyaluronic acid from about 0.1 micrograms to about 400 micrograms per kg of body weight of instant claim 1 is also anticipated by the Pierce patent because if 100Kg of body weight is used, the effective amount of hyaluronic acid is 40mg, which is within the range disclosed by Pierce. in addition, the single method step of claim 1 of Pierce is the same as applicant's.